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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/620,242 | 07/15/2003 | Ricky Ulrich | 003/267/SAP | 8917 |

7590 03/16/2006

ATTN: MCMR-JA (Ms. Elizabeth Arwine- PATENT ATTY)
U. S. Army Medical Research and Materiel Command
504 Scott Street
Fort Detrick, MD 21702-5012

| EXAMINER | |
|---|---|
| NAVARRO, ALBERT MARK | |
| **ART UNIT** | **PAPER NUMBER** |
| 1645 | |

DATE MAILED: 03/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/620,242 | ULRICH ET AL. | |
| | Examiner | Art Unit | |
| | Mark Navarro | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-63 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-63 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, 19, 21, 23, 26, 28, 30 and 32, drawn to DNA encoding a B. mallei AHS protein, classified in class 536, subclass 23.7.

II. Claims 4-8, drawn to DNA encoding a B. mallei LuxR transcription regulator, classified in class 536, subclass 23.7.

III. Claims 9-12, 20, 22, 24-25, 27, 29 and 31, drawn to DNA encoding a B. pseudomallei AHS protein, classified in class 536, subclass 23.7.

IV. Claim13-18, drawn to DNA which encodes a B. pseudomallei LuxR transcriptional regulator, classified in class 536, subclass 23.7.

V. Claims 33 and 37, drawn to a B. mallei AHS peptide, classified in class 530, subclass 350.

VI. Claims 34 and 38, drawn to a B. ballei LuxR peptide, classified in class 530, subclass 350.

VII. Claims 35 and 39, drawn to a B. pseudomallei AHS peptide, classified in class 530, subclass 350.

VIII. Claims 36 and 40, drawn to a B. pseudomallei LuxR peptide, classified in class 530, subclass 350.

IX. Claims 41-42, drawn to an antibody, classified in class 530, subclass 387.1.

X. Claim 43, drawn to a method for screening agents which reduce B. mallei virulence, classified in class 435, subclass 7.1.

XI. Claims 44-45, drawn to drugs which inhibit B. mallei Bmal3 enzyme activity, classified in class 514, subclass 2.

XII. Claim 46, drawn to a method of detecting bpml2 via PCR, classified in class 435, subclass 6.

XIII. Claim 47, drawn to kits comprising primers specific for bmal3, classified in class 435, subclass 975.

XIV. Claim 48, drawn to methods for treatment of B. mallei, classified in class 424, subclass 184.1.

XV. Claims 49-54, 56, and 58-60, drawn to a B. mallei strain with a mutated Bmal3 gene, classified in class 435, subclass 252.3.

XVI. Claims 55 and 57, drawn to a B. pseudomallei strain with a mutated bpml3 gene, classified in class 435, subclass 252.3.

XVII. Claim 61, drawn to a method of eliciting a B. mallei immune response, classified in class 424, subclass 93.1.

XVIII. Claim 62, drawn to a kit of primers specific for Burkholderia, classified in class 435, subclass 975.

XIX. Claim 63, drawn to a method for distinguishing between B. mallei and B. pseudomallei, classified in class 435, subclass 7.4.

**Additionally Groups I-XIX are further restricted as set forth in MPEP 803.04, which sets forth that biological molecules with distinct sequences are distinct inventions. Accordingly, Applicant is restricted to a single SEQ ID NO for examination.**

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV are all distinct as they are all DNA molecules encoding separate proteins from separate organisms with a distinct structure.

Invention I-IV, drawn to DNA, and Inventions V-VIII, drawn to polypeptides are distinct since they are products with different structure and biological properties. The protein is made of amino acids whereas the nucleic acid consists of nucleotides. Further methods known in the art used to make the polypeptide require different reagents and parameters from the methods of making the nucleic acid encoding the protein and the method of making the polypeptide does not require the nucleic acid. For instance, the protein can be made by Merrifield chemical synthesis or affinity chromatography.

Inventions V-VIII are all distinct as they are all molecules with a distinct primary, secondary and tertiary structure.

Invention IX, drawn to an antibody is distinct from Inventions I-VIII and X-XIX since it has an inherent affinity, avidity, and specificity for a given epitope.

Invention X, drawn to methods of screening agents is distinct from Inventions I-IX and XI-XIX since it requires additional biological reagents and parameters for detecting the agent.

Invention XI, drawn to drugs is distinct from Inventions I-X and XII-XIX since it has a unique primary, secondary and tertiary structure.

Invention XII, drawn to methods of detecting bpml2 via PCR is distinct from Inventions I-XI and XIII-XIX since it requires additional biological reagents and parameters for detecting bpml2.

Invention XIII, drawn to primers specific for bmal3 is distinct from Inventions I-XII and XIV-XIX since it requires specific probes for bmal3.

Invention XIV, drawn to methods for treatment of B. mallei is distinct from Inventions I-XIII and XV-XIX since it requires additional biological reagents and parameters.

Invention XV, drawn to a B. mallei strain with a mutated Bmal3 gene, is distinct from Inventions I-XIV and XVI-XIX since it requires a specific mutation.

Invention XVI, drawn to B. pseudomallei strain with a mutated bpml3 is distinct from Inventions I-XV and XVII-XIX since it requires a specific mutation.

Invention XVII, drawn to method of eliciting a B. mallei immune response is distinct from Inventions I-XVI and XVIII-XIX since it requires additional biological reagents and parameters.

Invention XVIII, drawn to kit of primers specific for Burkholderia is distinct from Inventions I-XVII and XIX since it requires specific probes for Burkholderia.

Invention XIX, drawn to a method for distinguishing between B. mallei and B. pseudomallei is distinct from Inventions I-XVIII since it requires additional biological reagents and parameters.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Navarro
Primary Examiner
March 9, 2006